

OCT 25 1995



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Re: Patent Term Extension
Application for
U.S. Patent No. 4,844,882

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,844,882 issued July 4, 1989, which claims the medical device ALBUNEX, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 762 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of March 2, 1995. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase) + Approval Phase} \\ &= 1/2 (975 - 537) + 1422 \\ &= 1641 \text{ days}\end{aligned}$$

Since the regulatory review period began January 14, 1988, before the patent issued (July 4, 1989), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From January 14, 1988 to July 4, 1989 is 537 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $975 - 537 = 438$ days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (August 5, 1994) when added to the period of extension calculated above (1641 days) cannot exceed fourteen years. The period of extension is thus limited to August 5, 2008, by operation of 35 U.S.C. § 156(c)(3). Since the patent term of seventeen years (35 U.S.C. § 154) would expire on July 4, 2006, the period of extension is the number of days to extend the term of the patent from its expiration date to and including August 5, 2008, or 762 days.

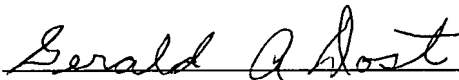
The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of

the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 762 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,844,882
Granted:	July 4, 1989
Applicant:	Kenneth J. Widder
Owner of Record:	Molecular Biosystems, Inc.
Title:	CONCENTRATED STABILIZED MICROBUBBLE-TYPE ULTRASONIC IMAGING AGENT
Classification:	424/9.52
Product Trade Name:	ALBUNEX
Term Extended:	762 days


Gerald A. Dost
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: ALBUNEX
FDA Docket No. 94E-0360